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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/808,982 | 03/25/2004 | Carl A. Caspers | 55508-296809 | 7038 |

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FAEGRE & BENSON LLP
PATENT DOCKETING - INTELLECTUAL PROPERTY
2200 WELLS FARGO CENTER
90 SOUTH SEVENTH STREET
MINNEAPOLIS, MN 55402-3901

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| EXAMINER |
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WILLSE, DAVID H

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| ART UNIT | PAPER NUMBER |
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3738

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| NOTIFICATION DATE | DELIVERY MODE |
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01/05/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

djohnson2@faegre.com
rhale@faegre.com
PatentDocketing@Faegre.com

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/808,982 | CASPERS, CARL A. | |
| | Examiner | Art Unit | |
| | David H. Willse | 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-23, 26-36 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-23, 26-36 and 38-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9-13-2010; 12-13-2010</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3738

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-23, 26-35, and 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 21, the pump being “attached to the apparatus” (line 8) along with the pump itself being part of said apparatus (claim 21, lines 1, 2, and 8) is confusing and somewhat contradictory and thus renders the claimed scope to be indefinite. Similar problems exist in claims 29 and 31 at lines 1-2 of each and in claim 35 at lines 7 and 12. In claim 31, line 3, “the vacuum in the space” lacks a proper antecedent basis. Claim 41 depends from a canceled claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-23, 26, 27, and 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Slemker, US 5,702,489, which discloses a flexible liner comprising a non-porous material (column 5, lines 53-58) adapted to cover the residual limb portion received in the cavity of a single socket **12** and **28** (Figure 1; column 2, lines 29-30; column 4, lines 9-11 and 30-52)

Art Unit: 3738

and a vacuum source (column 6, lines 28-30) in fluid communication with spaces **36** and part of interior **24**. The vacuum source includes a vacuum tube (column 5, lines 9-10) attached at one end to a vacuum valve **58** (or **64** and **65**; column 5, lines 8-18; Figure 1) and at the other end to a pump, which is inherently attached to, for example, its own housing and vacuum tube coupling (both of which may be viewed as part of the “apparatus”). The vacuum source is in spatially continuous (i.e., uninterrupted) fluid communication with said spaces, is in temporally continuous fluid communication as the liner and residual limb portion are inserted or received into the cavity, and is capable, whether or not such was the intent, of being in temporally continuous fluid communication with said spaces during ambulation because the amputee can simply hold onto the “hand-held pump” (column 6, line 24) during a test run, for instance. Regarding claim 22, attention is directed to column 1, lines 20-21; column 3, lines 63-65; etc. Regarding claims 27 and others, reference is made to column 6, lines 24-25. Regarding claim 33, the pump is indirectly attached to the prosthetic limb member **14** via the vacuum tube and via the amputee holding said pump (during donning or doffing, for example).

Claims 28-32, 34-36, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slemker, US 5,702,489. Regarding claim 28, a motor-driven pump would have been immediately obvious from the hand-held and electronically controlled embodiments contemplated at column 6, lines 24-25. Regarding claims 30 and others, a battery would have been obvious in order to perform donning and doffing at remote locations. Regarding claims 31 and 35, a regulator would have been inherent from the electronic control (column 6, line 25) in order to impart and maintain the desired level or range of negative or positive pressure when the apparatus is in use for donning or doffing. Regarding claims 34 and 39, an integral annular seal

Art Unit: 3738

outwardly projecting from the silicone liner would have been an obvious modification in order to facilitate the donning of the prosthetic limb and to better maintain suction. Regarding claim 36, maintaining application of the vacuum in said spaces to values within the range of 10 to 25 inches of mercury during use as a donning facilitator would have been obvious to the ordinary practitioner using routine experimentation in order to provide a comfortable yet sufficient suction force, and automatically adjusting the applied vacuum as the residual limb end approaches the interface cushion **28** of the socket would have been obvious in order to avoid traumatic impact forces or other discomfort; moreover, the optional valve discussed at column 5, lines 21-32, automatically adjusts the vacuum during ambulation. Regarding claim 40, porous suspension sleeves were well known in the art at the time of the present invention and would have been obvious in order to supplement the securement between the residual limb and the socket.

The Applicant's remarks have been considered and are addressed in the above grounds of rejection.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114 (MPEP § 706.07(b)). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 3738

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday through Thursday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**/David H. Willse/
Primary Examiner
Art Unit 3738**